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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,861	09/24/2003	Donald A. Schon	MED-0005D1	9768

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EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/670,861

Applicant(s)

SCHON ET AL.

Examiner

Melanie J. Hand

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 22-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/24/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for priority as a continuation-in-part of copending Application No. 09/585,149 filed on June 1, 2000, issued as Patent No. 6,719,749.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 24, 2003 was filed after the mailing date of the Application on September 24, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22-25, 27-30 and 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Ash et al (U.S. Patent No. 5,947,953).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C.

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102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With respect to **Claim 22**: Ash teaches a double catheter assembly 10 having a proximal and distal region, a first catheter 26 and second catheter 30 with first and second lumens 28 and 32 attached by a membrane 46 to form a unitary catheter tube defined by the two separable catheters. Membrane 46 allows partial splitting of catheters 26 and 30 along a longitudinal axis L.

With respect to **Claims 23,25**: Ash teaches that the catheter assembly 10 has a generally circular cross-section and that the catheters 26,30 have a semi-circular cross section wherein respective flat surfaces 38,44 are facing one another therefore the cross section of assembly 10 would be oval. (Fig. 4F) (Col. 6, lines 1-8, Col. 7, lines 31-35)

With respect to **Claim 24**: Ash teaches that the cross sections of lumens 28,32 are circular. (Col. 7, lines 31-37)

With respect to **Claims 27,28**: Please see the rejections of claims 22 and 23 as these rejections collectively address the limitations of claims 27 and 28.

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With respect to **Claims 29,30**: Ash teaches separating catheters 26 and 30 along a portion of membrane 46 wherein the length of the split region is greater than the unitary region. (Fig. 1) (Col. 6, lines 42-45)

With respect to **Claim 33,34**: Ash teaches that the cannulating portion 20 of catheter assembly 10 is formed from an extrusion process. (Col. 12, lines 38-41)

With respect to **Claim 35**: Please see the rejections of claims 22, 29,30 as these rejections collectively address all of the limitations of claim 35.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash et al ('953).

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With respect to **Claim 26**: Ash teaches that the cannulating portion 20 is formed in a single extrusion process yielding catheters with a semicircular cross section and therefore does not teach a separate finishing process to produce said cross section. Examiner asserts that the extrusion process produces an identical structural feature to a separate finishing procedure, i.e. the cross section, and is therefore an obvious modification to the prior art of Ash. Rejection under 35 U.S.C. 103 is indicated where prior art discloses product that appears to be either identical with or only slightly different from product claimed in product-by-process claim. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash ('953) in view of Melsky et al (U.S. Patent No. 5,704,915).

With respect to **Claims 31,32**: Ash does not teach grinding or polishing the cannulating portion 20 of catheter assembly 10. Melsky teaches a hemodialysis access device comprised of a catheter with a proximal and distal end where the distal end is split into two conduits. Melsky teaches pumping a slurry of abrasive material through shells 22 and polishing the subsequently smoothed surfaces of conical shells 22 and outlet tubes 32. Melsky teaches that it is desirable to have blood contacting surfaces be as smooth as possible to avoid thrombus formation and blood cell damage. ('915, Col. 5, lines 13-22) Since the assembly taught by Ash is also used for hemodialysis (Col. 5, lines 42-44), it would be obvious to one of ordinary skill in the art to grind and polish the outside surfaces of the catheter assembly taught by Ash.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', written over the printed name and title.